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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,786	02/06/2004	Kenneth A. Alley	ALLE-P11-US	7917

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EXAMINER

HAND, MELANIE JO

ART UNIT PAPER NUMBER

3761

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/773,786

Applicant(s)

ALLEY, KENNETH A.

Examiner

Melanie J. Hand

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/30/04</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's arguments, see Remarks, filed July 12, 2006, with respect to the election/restriction requirement have been fully considered and are persuasive. The requirement has been withdrawn.

### ***Priority***

Acknowledgment is made of applicant's claim for priority under copending Provisional Application No. 60/445,256, filed on February 6, 2003.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on July 30, 2004 was filed after the mailing date of the Application on February 6, 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for

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purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 10-14, 16 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Severin et al (U.S. Patent No. 6,488,665):

With respect to **Claim 1**: Severin teaches an applicator comprising a container 14 having an open end with opening 20 and a closed end, a barrier 22 positioned proximate opening 20 for preventing the substance from escaping container 14, an applicator head 26 having delivery means 28, wherein the head 28 communicates with container 14. Threads 38 on container connector end 34 of container connector 24 allow removable attachment of the applicator head 28 with gel dispenser 16 (passageway for delivering liquid from container to delivery means 28) to the open end of container 14. A seal piercing member 30 (means associated with applicator head for piercing barrier 22) is disposed on the gel dispenser 16 such that the barrier 22 is opened after the applicator head 28 is attached to the container by manipulating the applicator head with respect to the container.

With respect to **Claim 2**: Delivery means 28 is an absorbent sponge-like pad.

With respect to **Claim 3**: A foam pad is considered herein to be sponge-like, as both a foam and a sponge are formed by identical processes.

With respect to **Claim 4**: A sponge-like pad is a hydrophilic absorbent material.

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With respect to **Claim 5**: Severin teaches that delivery means 28 has a soft texture for comfort and is suited for topical medical use, of which terry cloth is an example.

With respect to **Claim 6**: Barrier 22 is comprised of aluminum foil.

With respect to **Claim 7**: A seal piercing member 30 (means associated with applicator head for piercing barrier 22) is a projection disposed on the gel dispenser 16 such that the barrier 22 is opened after the applicator head 28 is attached to the container by manipulating the applicator head with respect to the container.

With respect to **Claim 10**: Container 14 is necessarily a single dose container due to the non-resealable nature of barrier 22.

With respect to **Claims 11-13**: Gel formulation 12 is a topical medicament for application to a user's skin. The formulation comprises alcohol and iodine, and is taught by Severin to also be a topical antiseptic for sterilizing a section of the skin.

With respect to **Claim 14**: Container 14 is prefilled with a desired amount of said formulation for a surgical procedure, i.e. a pre-measured substance.

With respect to **Claim 16**: Gel formulation 12 is a viscous substance.

With respect to **Claim 18**: Please see the rejection of claim 1 in addition to the following:

Container connector 24 is a section of system 10 that is tubular in shape and connects the pad

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28 (permanently connected to applicator 26) to the open end of container 14. Once the connector 24 is threadably engaged with the applicator 26 and applicator head 28, the resulting tubular section formed by connector 24 and applicator 26 (seen as applicator 26 in Fig. 1) doubles as a handle for allowing a user to grasp and manipulate the applicator head. Upon manipulation of the applicator head in a specific manner to open barrier 22, the formulation 12 is released into container connector 24 attached to applicator 26 (collectively, the tubular section) and allowed to be absorbed into pad 28.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Severin et al (U.S. Patent No. 6,488,665).

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With respect to **Claim 15**: Severin does not explicitly teach that delivery system 10 is sold and/or delivered in a tamper-proof packaging, however it would be obvious to one of ordinary skill in the art to provide such a packaging for system 10, as the individual systems have a one-time use in surgical procedures, thus they are prone to tampering and are used in sterile environments and the systems 10 are therefore required to be sterile themselves.

With respect to **Claims 17,19**: Severin does not teach a powdered substance or a liquid, however container 14 is capable of holding such substances, and the delivery means is capable of transporting a powder to the applicator head where such powder would be administered to a user's skin, therefore it would be obvious to one of ordinary skill in the art to use the delivery system taught by Severin to deliver a powdered formulation or a liquid formulation as opposed to a gel formulation.

Claims 8, 9, 15, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Severin et al (U.S. Patent No. 6,488,665) in view of Macartney et al (U.S. Patent No. 5,306,270).

With respect to **Claims 8,9**: Severin does not explicitly teach a plug comprised of plastic material penetratable by a piercing element. Macartney teaches a sealing closure plug cap 18 comprised of thermoplastic elastomeric material (i.e. plastic) and having an opening for accepting a needle. Macartney teaches that the plug provides an airtight seal about the opening of a vial or tube, therefore it would be obvious to one of ordinary skill in the art to substitute a plug as taught by Macartney for the foil liner barrier taught by Severin with a reasonable

expectation of success, as such a plug is also capable of creating a gas-impermeable seal that prevents the gel taught by Severin from escaping its container.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand  
Examiner  
Art Unit 3761

MJH  
September 23, 2006

TATYANA ZALUKAEVA  
SUPERVISOR, PRIMARY EXAMINER

